

1. Product description:

Dental reusable surgical instruments made of Stainless steel or Titanium alloy (hereby under: 'Instruments').

Instruments name	Raw material	Number of uses	
Fixation pins	Titanium alloy grade 23 (Ti6Al4V ELI) per ASTM F136	20 cycles of use	
Anchoring screws	SS420 per ASTM A276/A276M	20 cycles of use	
Description	Procedure		
Fixation pins	Fixation pins and anchoring screws are used in guided surgery in fully edentulous cases or if template stability cannot be guaranteed. Insert the fixation pins through the fixation pin sleeves in the surgical guide and manually screw them to the full length of the thread. Place the anchor screw manually through the guide sleeve. If needed, secure the screw using a ratchet until the stopper touches the sleeve.		
Anchoring screws			

2. Intended use:

Ditron Implant instruments are intended to be used for dental implant placement procedures in the bone of the upper or lower jaw arches, and in prosthetic restoration procedures. Allowing for the insertion on the dental implant/s in a controlled way.

3. Intended clinical benefits:

The correct use of Dental instruments allows for the insertion on the dental implant/s in a controlled and stable way.

4. Target population:

1. Patient population: Edentulous or partially edentulous adult patients' population who require tooth replacement in dental rehabilitation and to whom none of the specified contraindications apply.
2. Intended users: Ditron Dental Instruments are to be used only by a licensed dentist (DMD/DDS) who has the specialization, skills and appropriate training in dental implants and restoration in order to assure successful treatment. Rx Only. Federal law restricts this device for sale by or on the order of a dentist or a licensed practitioner

5. Indication:

For fully Edentulous cases or if template stability cannot be guaranteed who require tooth replacement using a surgical template in dental rehabilitation and to whom none of the specified contraindications apply.

6. Contraindications:

Customary observation should be made of the contraindication associated with tools material used in oral surgery. The patient's general health and suitability for oral surgery must be assessed by the general practitioner.

- Patients who are medically unfit for oral surgery. Ditron Dental Instruments should not be used in patients suffering from physiological, medical, and/or anatomic conditions (such as: cleft of the alveolus and palate, uncontrolled diabetes, uncontrolled blood pressure, unstable respiratory diseases, patients who are exposed to radiation treatments, etc.) that may negatively affect healing.
- Following current accepted knowledge and technology, dental Instruments should not be used in patients suffering from bone disease, insufficient alveolar bone width and height surrounding the drill site or who are using anti bone turnover medications, hypersensitivity or allergy to Titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), Stainless steel.
- Physiological, medical, and anatomic conditions may negatively affect the implant placement procedure and implant performances. These Instruments are intended for use only by certified dentists and authorized personnel with specific implant training.
- Customary observation should be made of the contraindication associated with tools material used in oral surgery. The patient's general health and suitability for oral surgery must be assessed by the general practitioner.

CAUTION Rx only: US Federal law restricts this device for sale by or on the order of a dental professional. These devices are intended for use only by certified dentists and authorized personnel with specific implant training. Product availability may vary between countries according to regulations approvals.

7. Warning & Precautions:

- Ditron Dental's Instrument are to be used only by a licensed dentist and authorized personnel, who has the specialization, skills and appropriate training in dental implants and restoration in order to assure successful treatment. Lack of adequate training of the practitioner is a major risk factor for the success of the implant procedure and may endanger patient health.
- Failure to plan and prepare implant and/or fixation site position and depth correctly can result in harm to nerves, blood vessels, teeth, or other sensitive structures. Incorrect instrument settings or excessive installation torque can result in failed implant or fracture of the jawbone.
- Allergy or hypersensitivity to chemical ingredients of material used. The patient's health history must be carefully assessed.
- Always wear Gloves when handling contaminated instruments. Eye protection must be worn to protect against ejected particles. A surgical mask must be worn to avoid inhalation of aerosol or dust generated.
- Do not use, if the Ditron package has been damaged or opened. Inspect the instruments for damage or wear before each use and discard/return to manufacturer defective instruments.
- The products are provided non-sterile. Clean, disinfect and sterilize the instruments in accordance with the directions below before first use and before each reuse, in order to avoid contamination.
- Use of non-sterile components may lead to infection of tissues or infectious diseases.
- Over time, repeat sterilizations may affect instruments' efficiency and color appearance. Cutting edges should present a continuous edge and appear sharp. If the inspection reveals signs of wear, damage, or unrecognizable color identification, replace the continuous immediately.
- Instruments should be replaced after 20 cycles of use. Blunt or damaged instruments must be replaced immediately. Inspect the Instrument for damage or wear before each use and discard/return to manufacturer defective tools.
- For all metal instruments, it is recommended to use anticorrosive disinfecting and cleaning agents. They should be free of: Aldehyde, Ethanolamine, chlorine, and acid. All instruments that are used intraorally must be secured to prevent aspiration or swallowing. Ensure that the tool is fully seated and gripped before use.
- Avoid contact when cleaning, disinfecting, and sterilizing instruments from different materials Use only specifically formulated for dental cleaning and disinfectant agents.

8. Risks and Potential Adverse Events

The dental literature indicates that the following are potential adverse events related to the placement and restoration of dental implants: nerve injury, perforation of the maxillary sinus, perforation of maxillary or mandibular bone, loss of integration, failure of implant, dehiscence, delayed healing, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, implant breakage or fracture of implant or components. Although some of these adverse events are incurable, many may require additional surgical procedures for their resolution. Implant placement procedure is a surgical procedure performed in the oral cavity, and as such, the patient is exposed to the risks associated with intraoral surgical procedures. Such as Allergic or hypersensitivity reactions to materials used, Patients must be informed of all potential risks and provide a conscious, written consent for the procedure.

9. Cleaning and sterilization instructions:

Correct and careful maintenance of Ditron Dental instruments is extremely important. Cleaning can be done manually or by using automated washer unit.

9.1. Manual cleaning:

- Never let surgical residues (blood, debris) dry on instrument, clean immediately after surgery.
- Prepare a neutral/mild pH enzymatic detergent (Deconex® POWER ZYME concentration of 5ml/l or equivalent) according to the manufacturer's instructions.
- Rinse the instrument under a hard stream of lukewarm water for a minimum of one (1) min. Avoid water with high concentration of chlorine. Warning: Use sterile water (from a sterile labeled container/bag), unless the potable water is of low contamination and meet all applicable local laws and regulation
- Immediately soak in a detergent solution for a minimum of ten (10) minutes.
- Use a soft-bristled, nylon brush to gently scrub the instrument during detergent soaking to remove any remaining blood or debris for a minimum of one (1) minute. While brushing, particular attention should be made to the grooves in the reachable exterior surfaces. Never clean instruments with metal brushes or steel wool. This can cause corrosion, deposition of metal particles, oxidation, etc.
- Rinse the instrument under running tap water for a minimum of (2) minutes.
- Fully dry on a clean cloth before sterilization. Prevent contact between instruments.

9.2. Automatic cleaning (Using automated washer unit):

- Never let surgical residues (blood, debris) dry on an instrument, clean immediately after surgery: pH Neutral Enzymatic detergent will be prepared according to manufacturer's instructions, at the lowest recommended concentrations and lowest recommended temperature. (Note: Deconex Power Zyme detergent manufacturer indicate recommended working temperature of 45-55°C for 10 min).
- Place the instrument in the automatic washer.
- Run the automatic wash cycle using neutral pH enzymatic detergent according to manufacturer's instructions (such as Deconex Powerzyme or equivalent). Per minimum/maximum short cycle parameters:
 - » 2 min cold prewash at 30 ±5°C (86±41°F) with tap water
 - » 10 min main wash with neutral pH detergent and tap water at 45 ±5°C (131±41°F)
 - » 10 min rinse 70°C (158°F) tap water
 - » 20 min air drying phase at high temperature of 100°C (212°F)
- » Place the instruments on a clean cloth to dry for a least 10 minutes

Note: At the end of the cleaning process, only distilled water should be used, in order to avoid surface stains or corrosion. Warning: Use sterile water (from sterile labeled container/bag), unless the potable water is of low contamination and meets all applicable local laws and regulations.

9.3. Sterilization:

- Wrap the instrument for sterilization with approved microbial barrier wraps (FDA Clearance in the US and CE Mark in EU)
- Sterilize the instruments by steam according to the autoclave's instructions.
- 121°C/250°F for a full exposure time of 30 minutes followed by a 15-minute dry cycle. Distilled water should be used in order to avoid surface stains. Make sure before use that the elements inside the autoclave, are not rusted.
- Chemoclave is NOT recommended.
- The sterilized devices are for immediate use. Do not store after sterilization. After sterilization, the products need to be transported to the point of use and stored in a pouch-sterile barrier system, kept dry and not exposed to direct sunlight.
- Inspect the parts after each preparatory treatment/cycle (cleaning, sterilization) to ensure proper functionality and safety. If you suspect a problem, do not use the instrument.

10. Storage and Disposal:

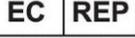
Storage: The device must be stored and transported in clean and dry condition in the original packaging and not exposed to direct sunlight. Store at room temperature. Incorrect storage and transportation may influence device characteristics leading to failure. **Disposal:** Disposed reusable surgical instruments should be handled as potentially contaminated products unless conclusive evidence exists to the contrary. Disposed surgical instruments and packaging must be disposed/discarded according to local environmental authority regulations (be aware of physical hazards due to sharp edges).

11. Symbols: interpretation: Symbols on the product package should be interpreted as follows:

Symbol	Description	Symbol	Description
	Medical Device	RX only	Prescription device
	Catalog number		Do not use if package is opened or damaged
	Lot number/Batch number		Non-sterile
	Use-by date		Keep dry
	Date of manufacture		Keep away from sunlight
	Manufacturer		CE-Mark
	Consult instructions for use or consult electronic instructions for use		Authorized representative in the European Community Community/European Union

NOTE. Inform Ditron and the competent authority (details below) in case of life-threatening or any serious incident that has occurred in relation to the device.

DISCLAIMER OF LIABILITY - The users of Ditron Dental products must determine whether or not a particular product is suitable for a particular application and circumstance. Ditron Dental disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages arising out of or in conjunction with any errors in professional judgment or practice in the use of Ditron Dental products. The devices are intended for use only by certified dentists and authorized personnel with specific implant training. Users are advised and obliged to study the latest news and developments in implant dentistry for any updates to products and/or specifications. Ditron Dental has no control over the use of its products, which are the responsibility of the user. Ditron Dental will assume no liability whatsoever for the damages arising thereof.

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